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UNITED STATES DEPARTMENT OF COMMERCE
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Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

Re: PRELAY™ and REZULIN™

FDA Docket No. 95N-0145

Dear Mr. Wilson:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 4,572,912. The application was filed on February 27, 1997, under 35 U.S.C. § 156.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

As to the regulatory review period, your letter to Stephen G. Kunin, dated May 21, 1997, states that PRELAY™ and REZULIN™ (troglitazone) were assigned NDA No. 20-719. However, the application for patent term extension shows that PRELAY™ was assigned NDA No. 20-719, whereas REZULIN™ was assigned NDA No. 20-720. But since applicant states that both NDAs were submitted on July 31, 1996, and approved on January 29, 1997, and since only one IND is relied upon, the length of the regulatory review period would appear to be the same regardless of the NDA used.

Telephone inquiries regarding this matter should be directed to the undersigned at (703)306-3159.

Karin Tyson
Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Herbert Goodman, Esq.
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